

Product Steward

Job ID
REQ-10017316
Ago 13, 2024
Turquía

Resumen

Responsible to maintain and improve the scientific oversight of the manufacturing processes and technical changes, the relevant technical knowledge and capabilities at the Site and to ensure the product and technical stewardship, across process units and functions at Site.

About the Role

- Own the process knowledge of the product(s) assigned throughout the commercial lifecycle, maintains the oversight on process capability, through data trending and statistical analysis of critical parameters, ensuring process(es) are robust, in continued state of validation and continuously improving.
- Ensure seamless flow of knowledge and information across functions and with other Sites when applicable, with focus on the product(s). Provide second line technical/scientific process support.
- Initiate and support investigations and improvement projects (quality, efficiency), based on the data analysis, involving cross-functional teams.
- Evaluate the effect of manufacturer changes of drug substances and excipients on drug product quality.
- Support Validation Lead and Experts to assess need and plan validations / re-validations / verifications, consulting approving and reviewing the process validation master plan, together with the

Minimum Requirements:

- BSc. in Pharmacy, Pharmaceutical Technology, Chemistry or equivalent scientific degree
- Desirable MSc. or equivalent experience
- Fluent in English and proficient in site local language
- Minimum 4 years experience in process support, e.g. Process Expert role on the shopfloor of pharmaceutical manufacturing and/or QA/QC
- Proven process understanding (Pharma, GMP, Regulatory aspects)
- Sound experience of data handling and applied statistics is a must

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División

Operations

Business Unit

Innovative Medicines

Ubicación

Turquía

Sitio

İstanbul Kurtköy

Company / Legal Entity

TR01 (FCRS = TR001) Novartis Sağlık, Gıda ve Tarım Ürünleri San. Ve Tic. A.Ş.

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

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